

# The keys to success in patent litigation

Winning a patent litigation suit can be tricky – but by taking various key factors into account, rights holders can boost their chances of success

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A patent portfolio has always been key to the technological and economic development of any innovative company, but in the past there have been relatively few patent infringement litigations. However, with enhanced competition and significant potential economic benefits to be reaped from innovation, technology and the commercial exploitation of patents, skirmishes for the right to manufacture successful products are leading to an increasing number of patent litigations. Therefore, it has become crucial not only to obtain a patent for an innovation, but also to develop ways to protect against invalidation and prevent infringement. This depends on having well-planned patent litigation strategies in place.

The burning question is: what is the key to success in patent litigation? Various factors are collectively important in order to succeed, and it is difficult to select just one or two. Such factors include:

- the validity of the patent;
- the diligence of its prosecution;
- the analysis of relevant prior art;
- the compilation of evidence; and
- the presentation of the case before the court.

Each factor requires technical and legal expertise, skill and laborious preparation – which explains why only a handful of attorneys have successful patent practices.

## Establishing invalidity

More often than not, a patent infringement suit is lost on the grounds of invalidation of the patent – even though the patent was granted by a patent office after examination by its technically qualified examiners and despite the opportunity granted to members of public to oppose the patent. The courts have concurrent jurisdiction to investigate the validity of a patent in an infringement action. One key defence raised by parties sued for infringement of a patent is invalidity, however weak such plea may be. The reason is simple: the trial process, which involves the cross-examination of witnesses, may strengthen a weak plea of invalidity. It is therefore essential for both parties to prepare their evidence by way of testimony which can withstand the rigours of cross-examination. As no evidence can be presented in respect of any fact or issue which has not been cited by the parties in the pleadings filed before the court, it is vital to draft pleadings in a patent infringement action carefully and comprehensively. It is important not only to make full disclosure of all relevant material facts, but also to deal with such issues as may be raised in anticipation by a contesting party. Hence, the first key to success in a patent litigation is the skilful preparation of pleadings and evidence before commencement of the litigation.

In some jurisdictions, once a patent has been granted its validity is assumed in favour of the patentee – but this is not the case in India. However, there is serious doubt as to the correctness of such view, and even the Indian courts recognise that the onus to prove invalidity must be on the contesting party rather than the patentee. To that extent, the burden imposed on the patentee is only

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to rebut the plea of invalidity raised by the contesting party. The burden of proving infringement, however, lies squarely with the patentee. Hence, when initiating patent infringement litigation, the burden is on the patentee to plead and prove the issue of infringement. A deficient pleading or a lack of evidence will lead to dismissal of the patent infringement suit, even if the validity of the patent is upheld.

In order for a patent to be held valid, it must fulfil the following tests:

- It must be new.
- It must be “capable of being made or used in any industry”.
- It must fulfil the requirement of being an invention, on account of technical advancement on existing knowledge or economic significance.
- Its inventive step should not be obvious to persons skilled in the art.

Not every invention is patentable in India. Hence, in order to overcome a plea of invalidity, a patent must be established to be an ‘invention’, as well as being patentable. Among others, the following are not patentable:

- inventions which claim something that is obviously contrary to well-established natural law, contrary to public order or morality or harmful to human, animal or plant life or the environment;
- the mere discovery of a principle or formulation of abstract theory, or the discovery of any living or non-living substance occurring in nature or a new

form of a known substance which does not result in enhanced efficacy;

- admixtures resulting in the aggregation of properties of components or processes, the production of such substances or the mere arrangement, rearrangement or duplication of known devices, each functioning independently; and
- methods of agriculture or horticulture or any process for the diagnostic or therapeutic treatment of human beings or animals.

### **Asserting enhanced efficacy**

A key issue of the patentability of a pharmaceutical invention recently arose before the Supreme Court in *Novartis*, which involved Novartis’s Imatinib Mesylate, marketed as Gleevec. The issue pertained to Section 3(d) of the Patent Act 1970, which prohibits the grant of a patent for an invention comprising the discovery of a new form of a known substance which does not result in enhanced efficacy. The Supreme Court observed that the legislature has set the inventive step threshold higher for pharmaceuticals than for other patentable substances. The Supreme Court further held that the requirement of enhanced efficacy for a patentable invention comprising a new form of a known substance is fulfilled only when it is proven to be enhanced therapeutic efficacy. However, there was no clarification of the meaning and scope of ‘enhanced therapeutic efficacy’. Does an invention leading to reduced dosage constitute enhanced therapeutic efficacy? What about an invention leading to reduced toxicity? The court further observed

that the therapeutic efficacy of a medicine must be judged “strictly and narrowly”. The court stated that, with regard to the contention that an increase in bio-availability would lead to enhanced therapeutic efficacy, this must be specifically claimed and established by research data. The effect of these observations and the tests laid down by the Supreme Court remains to be seen, and will be tested in future patent infringement cases involving similar issues. However, there is no doubt that the observations and tests laid down by the Supreme Court require further clarification and elaboration.

### **Considering novelty and inventive step**

In order for an invention to be patentable, it must be new on the date of application for grant of the patent and must not have been previously published. Prior publication has been interpreted to mean that the invention is publicly known or accessible. The disclosure or coverage of the inventive step in any publication, patent specifications or research material available to the public before the priority date of the patent is sufficient to invalidate an otherwise valid patent. It is therefore critical to success in a patent litigation that the patent have been applied for before being made public.

Alongside the test of novelty, it is also essential for a patent to prove that inventive step is involved. Mere novelty is insufficient to enforce a patent. The test of novelty varies across jurisdictions. However, in India, the inventive step test laid down in the *Windsurfing* case applies, which involves taking the following steps in order to determine patentability:

- Identify the inventive step and concept embodied in the patent;
- Impute to an person with normal skill in the state of the art concerned, but with unimaginative faculty, what was common general knowledge in such state of the art at the priority date;
- Identify the differences between what was subject matter of common knowledge and the disclosure contained in the invention; and
- Determine whether such differences, when viewed without knowledge of the alleged invention, constitute steps that would be obvious to the skilled person, or whether they required invention.

As the US Supreme Court has observed, obviousness should be determined by looking at objective evidence of non-obviousness, which includes:

- commercial success;
- long-felt but unsolved needs; and
- failure of others

The above inventive step test has withstood the scrutiny of the courts for decades compared to the ‘teaching, suggestion, motivation’ test, which was recently revisited by the US Supreme Court in *KSR International*. In that case the court held that such test was restrictive and emphasised the need to scrutinise carefully whether the patent claims are obvious. The obviousness analysis cannot be confined to a formalistic conception of ‘teaching, suggestion, motivation’, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and modern technology counsels against limiting the analysis in this way.

In some patent litigations the patent at issue may also be the subject matter of corresponding patents in several other jurisdictions. It is imperative that the applicant disclose all such corresponding patents to the controller when applying for the patent grant. If this statutory requirement is not complied with, the court can invalidate the patent. How strict the courts should be in requiring full compliance with this statutory requirement is the subject of heated debate in India. It is understandable that a patent may be invalidated on account of non-disclosure of corresponding patents if, after examination in those jurisdictions, the patents were rejected, as this would have a bearing on the grant of the same patent in India. However, if such disclosures, although made subsequently, do not affect the validity of the patent on merit, it seems harsh to deny the patent to a rightful patentee on this ground alone.

### **Seeking preliminary injunctions**

In most patent litigations, it is preferable to seek a preliminary injunction if the patentee has a *prima facie* valid patent and has established a *prima facie* case of infringement.

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Once granted, a patent confers a monopolistic right. Although a patent is valid for 20 years from the date of application, prosecution of the patent invariably takes up a substantial chunk of that period. Therefore, it is essential that once the patent is granted, the patentee have sufficient time to exploit it commercially as reward for disclosing its invention to the public at large. For the same reason, if a patentee has chosen not to exploit its patent commercially by working it in India, it would not be entitled to a preliminary injunction.

When examining the issue of preliminary injunctions, the courts have consistently taken the view that a contesting party need not establish the invalidity of the patent at the interim stage of proceedings. It is sufficient for it to establish a credible challenge to the validity of the patent; if it does so, the court will decline a preliminary injunction request and leave the issue of invalidity to be determined at trial. If the patent is invalid, the issue of infringement is not examined. However, if the contesting party fails to raise a credible challenge to the patent's validity, the court will examine the issue of infringement; if it is satisfied, it will apply the principle set out in *American Cyanamide* and examine the balance of convenience and irreparable injury. The court will grant a preliminary injunction in favour of the patentee if the patentee can establish that:

- it would suffer irreparable injury by way of lost opportunity to exploit the patented invention commercially;
- it already has a sizeable market share which would be diluted by the manufacture or sale of competing goods; or
- it will fail to grant licences for the use of its patented invention and recover its investment in the research, development, marketing and promotion of the patented product,

If granted, a preliminary injunction significantly determines the fate of the patent litigation. Many cases are settled at this interim stage of the proceedings, without the patentee having to proceed to trial.

### **Succeeding at trial**

The real test of patent infringement litigation arises at trial, where the parties must produce

their witnesses for cross-examination.

Careful preparation for the trial, involving the preparation of testimonial affidavits and the production of documents on which the patentee wishes to rely as evidence, is essential and key to success. Cross-examination of witnesses is a skilful art practised by good attorneys, who bear in mind that cross-examination is a double-edged sword. After a satisfactory trial, it is equally essential to formulate arguments and submissions and to present them in an effective manner at the final hearing. Hence, a large number of factors must come together in order to succeed in a patent litigation, with each being a significant milestone towards achieving the ultimate goal of victory. ●●●●●

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